

K212367 IMRIS iMRI 3T VAug 23, 2021
24 days to decisionK212367 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k212367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 30, 2021
Decision date	Aug 23, 2021
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Deerfield Imaging, Inc.
Location	Minnetonka, MN, US
Contact	Tacy Brinkmeyer
510(k) history	2 submissions · 2 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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